

**Response Under 37 CFR § 1.116  
Expedited Procedure**

previous Office Action; (3) does not present any additional claims without canceling a corresponding number of finally rejected claims; and (5) places the application in better form for appeal, should an appeal be necessary. The amendment is necessary and was not earlier presented because it is made in response to arguments raised in the final rejection. Entry of the amendment is thus respectfully requested.

**I. The Drawings Comply With 37 C.F.R. § 1.84(P)(4)**

The drawings were objected to as failing to comply with 37 C.F.R. § 1.84(P)(4) because reference numeral "931" has been used to designate both the housing and the gel-like material in Fig. 39.

In response, Applicants respectfully submit that reference numeral "932" has been used in the specification to refer to the gel-like material. A somewhat illegible "932" has also been used in Fig. 39. To avoid any further confusion, Applicants submit simultaneously herewith a Request for Approval of Drawing Corrections, which clearly identifies reference numeral "932" in Fig. 39. No new matter is added. Applicants respectfully request reconsideration and withdrawal of this objection.

**II. The Claims Satisfy 35 U.S.C. § 112, Second Paragraph**

Claim 97 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended Claim 97 pursuant to Examiner's suggestion. Applicants

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respectfully submit that the amendments to Claim 97, if allowed, fully obviate the grounds for rejection and place the application in condition for allowance.

**III. The Claims Define Patentable Subject Matter**

Claims 82, 85-87, 96 and 97 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,599,305 to Hermann et al. (hereinafter, Hermann). Applicants respectfully traverse this rejection.

Herman teaches a large diameter introducer sheath having a foam insert 38 (see Fig. 8) in the sheath for surrounding and sealing the passage around surgical instruments introduced through the sheath. Hermann teaches that the foam insert has a lumen 52 which closes when the insert is confined within the housing. (Figs. 3 and 4; column 10, lines 4-9). Applicants respectfully submit that Hermann discloses a foam insert which has a preformed lumen. The surgical instruments introduced through the Hermann sheath are pushed through the preformed lumen of the foam insert.

Applicants have disclosed a smaller diameter introducer sheath having a sealing assembly filled with a biocompatible, gel-like sealing material. Applicants' material is not foam and does not have a preformed lumen, as taught by Hermann. Furthermore, the surgical components which are introduced during the surgical procedure are directly introduced through Applicants' gel-like material, not a preformed lumen.

Applicant maintains that the lumen of Hermann is always present, even if it is not apparent once the foam material is inserted into the sheath. It is conceivable that a small instrument could be inserted into the lumen of Hermann such that contact would not be complete and leakage may occur.

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For at least the reasons set forth above, Applicants respectfully submit that Hermann fails to disclose, teach or suggest the subject matter of the present invention. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully submit that the Claims of the present invention define subject matter patentable over the prior art of record, the claims satisfy the requirements of 35 U.S.C. § 112, second paragraph and the application is in condition for allowance. Should the Examiner believe anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number below listed.

Respectfully Submitted,

Date: November 13, 2000



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